REMARKS

Status of Claims

Claims 1 – 64 were original in the application. Claims 2 and 40 have been cancelled without prejudice. Claims 6 – 32, 34 – 39 and 41 – 46 have been withdrawn. Claims 1, 3 – 5 and 33 have been amended in this amendment. Claims 1, 3 – 5 and 33 as amended are submitted as being set forth in a clearly allowable condition or at least is a better form for appeal.

Request for Reconsideration of Restriction and Withdrawal of Claims

Prior counsel for applicant elected claims 1 – 5, 33 and 40 as drawn to Apparatus Species III[1] and Communications Link Species I. Claim 1 was asserted as generic. All claims depend on claim 1, which is the single independent claim in the application. Claims 1 – 5, 33 and 40 were designated as relating to the elected species, but an examination of the claims clearly indicates that claims 7 -10, 12, 36 and 48 also relate to a device that contains active control and regulation of the administration of medicating agents is attached to a synthetic pouch and **uses a piezoelectric valve and pump actuating mechanism**.

Hence, rejoinder of the withdrawn claims 7 -10, 12, 36 and 48 is renewed pursuant to MPEP 824.04.

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[1] The Examiner defined Species III as: "The device contains active control and regulation of the administration of medicating agents is attached to a synthetic pouch and **using a piezoelectric valve and pump actuating mechanism**." The Applicant misnamed the elected species as "Species II", when the designated claims 1 – 5, 33 and 40 in fact included the use of a piezoelectric valve and pump actuating mechanism.

Further, claim 1 being amended to no longer be generic, but to be directed to Species III, all withdrawn claims with the exception of claims 34 and 35, drawn to nonelected communications species, are dependent on claim 1, could properly be readable on the elected Species. Applicant respectfully request rejoinder of all withdrawn claims except for claims 34 and 35.

***Claim Rejections* - 35 *USC* § 112**

Claim 1 has been responsively amended.

Claim Rejections* - 35 *USC* § *102

Claims 1 - 5, 33 were rejected under 35 U.S.C. 102(e) as being anticipated by Flaherty US Patent 6,749,587.

The Examiner contended that Flaherty discloses an implantable apparatus comprising: an implantable (Fig 2, col 13, lns 12-43) pouch (10) having one or more chambers composed of a bioabsorbable material (30; col 22, lns 18-24); at least one medicating agent (col 3, lns 33-44) disposed in said one or more chambers; and at least one implantable piezoelectric pump (46, col 7, lns 32-33; col 15, lns 20-23) fabricated in the pouch which forms a skeleton of the pump, the pump being configured to transfer said at least one medicating agent to said patient (Summary); and an implantable, biocompatible and biodegradable skin (702, 802; col 9, lns 10-col 10, lns 8; col 22, lns 18-24) covering the pouch and pump; further comprising an implanted control circuit (50) to control said at least one piezoelectric pump to provide proper dosing and scheduling of said medicating agent in a closed loop control mode so that control of the

operation of the system is performed autonomously with local homeostatic parameters (col 11, Ins 13- col 12, Ins 3; col 13, Ins 12-42); a control circuit (50) to control said at least one piezoelectric pump to provide for infusing said medicating agent to a specific desired location such as at a tumor site; within a patient's body, and at least one implanted sensor (col 11, Ins 13-col 12, Ins 3; col 13, Ins 12-42) to measure a local homeostatic response related to the medicating agent, where the control circuit controls the piezoelectric pump to modify the state of the tumor in response to measurements from the implanted sensor (col 11, Ins 13-col 12, Ins 3; col 13, Ins 12-42); further comprising a control circuit (50) to control said at least one piezoelectric pump to provide for autonomously regulating, controlling, and modulating a combination therapy of cytokine and chemotherapeutic agents for the purpose of tumor elimination in a closed loop control mode (col 11, Ins 13-col 12, Ins 3; col 13, Ins 12-42); further comprising an implantable wireless bi-directional communications link (Fig 1; 60; 100; col 6, Ins 12-24) coupled to the implanted sensor through the implanted control circuit. 11.

Flaherty discloses an externally carried insulin pump where the apparatus 10 is externally secured to the patient as shown in Fig. 1. Each of the claimed elements in claim 1 require the respectively element to be implantable. Fluid is delivered from device 10 of Flaherty to the interior of the body only by means of a transcutaneous patient access tool, a cannula 72 for penetrating the skin of the patient. See col. 5, lines 19 – 26. The chambers of Flaherty holding the medicating agent are positioned outside the body and administered only through cannula 72 and are not implantable as required

by claim 1. The pump of Flaherty is outside the body and is not implantable as required by claim 1.

Col 13, lines 12-43, cited for showing an implanted device 10 disclose the opposite. Device 10 is described as being "on the body" with the possibility of communicating with a sensor through wireless RF, which sensor is implanted within the body. This necessarily means that being "on the body" is not in the body where the sensor is remotely implanted.

Flaherty fails to disclose an implantable and bioabsorbable skin covering the pouch and pump. Since device 10 is used exterior to the body, there is no reason for it to be absorbable or degradable within the body. It is clear that when Flaherty is describing the biodegradability of the housing 702, 802 it is referring to an environmentally friendly disposal and not absorption within the body. Flaherty states at col. 9, lines 50 – 59:

> The housings 702, 802 can be constructed of the same or different materials. For example, the housing 702 can be constructed of a more durable material to support longer intended life, while the housing 802 can be constructed of a softer or otherwise less durable material. In addition, the housing 802 of the disposable assembly may be constructed of a biodegradable material. Preferably, both of the housings 802, 702 are constructed of **biodegradable, recyclable or other environmentally friendly materials.**

These differences alone removes Flaherty as a reference for failure to disclose each and every element of the claim.

Claim 1 was also rejected as being anticipated by Johnson et al US Patent 6,541,021.

The Examiner contended that Johnson et al discloses an implantable apparatus comprising: an implantable pouch (Figs 1-4) having one or more chambers composed of a bioabsorbable material (col 10, lns 37-43); at least one medicating agent (Summary) disposed in said one or more chambers; and at least one implantable piezoelectric pump (col 7, lns 44; col 17, lns 53-67) fabricated in the pouch which forms a skeleton of the pump (Figs 2, 4), the pump being configured to transfer said at least one medicating agent to said patient (Summary); and an implantable, biocompatible and biodegradable skin (col 10, lns 37- 43) covering the pouch and pump.

Johnson refers to a controlled release of the drug from the device for pain treatment. Johnson defines what is meant by "controlled" at col. 7, lines 57 -61:

> The term **"controlled drug delivery device"** is meant to encompass any device wherein the release (e.g., rate, timing of release) of a drug or other desired substance contained therein is controlled by or determined by the device itself and not the environment of use.

No mention is made of an implanted control circuit to control the piezoelectric pump to provide proper dosing and scheduling of said medicating agent in a **closed loop control mode** so that control of the operation of the system is performed **autonomously with local homeostatic parameters** as required by amended claim 1. The use of local homeostatic parameters requires the control to be controlled by or determined by the environment of use. If a local parameter indicates that homeostasis is being lost in the environment of use during drug treatment, the closed loop control controls the delivery of the drug appropriately. Johnson teaches away from any such control or determination by the environment of use.

Further, no disclosure is provided with respect to use of any senor, nor any use of a sensor to established closed loop control based on homeostatic parameters. Johnson cannot be held to disclose each and every element of claim 1 as amended.

Claims 1 - 4, 33 were also rejected as being anticipated by Humes et . al US Patent Pub. 2002/0090388.

The Examiner contends that Humes et al discloses an implantable apparatus comprising: an implantable pouch ([0002]) having one or more chambers composed of a bioabsorbable material ([0003]); at least one medicating agent ([0011]) disposed in said one or more chambers; and at least one implantable piezoelectric pump ([0018, 0094, 0098]) fabricated in the pouch which forms a skeleton of the pump, the pump being configured to transfer said at least one medicating agent to said patient ([0018, 0078, 0094]); and an implantable, biocompatible and biodegradable skin ([0003, 0103-0109]) covering the pouch and pump; further comprising an implanted control circuit ([0094-0095]) to control said at least one piezoelectric pump to provide proper dosing and scheduling of said medicating agent in a closed loop control mode so that control of the operation of the system is performed autonomously with local homeostatic parameters ([0094-0095]); a control circuit ([0094-0095]) to control said at least one piezoelectric pump to provide for infusing said medicating agent to a specific desired location such as at a tumor site; within a patient's body, and at least one implanted sensor ([0094-0095]) to measure a local homeostatic response related to the medicating agent, where the control circuit controls the piezoelectric pump to modify the state of the tumor in response to measurements from the implanted sensor ([0094-

0095); further comprising an implantable wireless bi-directional communications link ([0094]) coupled to the implanted sensor through the implanted control circuit.

Humes discloses the use of an vascularly implanted stent containing a reservoir for drug release for systemic treatment. Humes is silent and discloses nothing regarding an implanted control circuit dosing and scheduling the delivery of the medicating agent in a closed loop control mode. Humes is silent and discloses nothing regarding relating to autonomously delivering the drug as determined by local homeostatic parameters. It cannot be held that Humes discloses each and every element of claim 1 as amended.

Claims 1 - 3 and 33 were also rejected as being anticipated by Soykan et al US Patent 6,206,914.

The Examiner contended that Soykan et al discloses an implantable apparatus comprising: an implantable pouch (Fig 1, 2, 5; Summary) having one or more chambers composed of a bioabsorbable material (col 9, lns 61-col 10, lns 3, 47-63); at least one medicating agent (Summary, col 13, lns 16-27) disposed in said one or more chambers; and at least one implantable piezoelectric pump (col 13, lns 16-27) fabricated in the pouch which forms a skeleton of the pump, the pump being configured to transfer said at least one medicating agent to said patient (col 13, lns 16-27); and an implantable, biocompatible and biodegradable skin (Figs 1, 2, Summary; col 9, lns 61-col 10, lns 3, 47-63) covering the pouch and pump; further comprising an implanted control circuit (Fig 5) to control said at least one piezoelectric pump to provide proper dosing and scheduling of said medicating agent in a closed loop control mode so that control of the

operation of the system is performed autonomously with local homeostatic parameters (Summary, col 15, Ins 13-col 16, Ins 11); a control circuit (Fig 5) to control said at least one piezoelectric pump to provide for infusing said medicating agent to a specific desired location such as at a tumor site; within a patient's body, and at least one implanted sensor (col 16, Ins 24-61) to measure a local homeostatic response related to the Page 7 medicating agent, where the control circuit controls the piezoelectric pump to modify the state of the tumor in response to measurements from the implanted sensor (col 15, Ins 13-col 16, Ins 61); further comprising an implantable wireless bi-directional communications link (col 15, Ins 13-58) coupled to the implanted sensor through the implanted control circuit.

Soykan is acknowledged as an implantable device that locally delivers a therapeutic agent. Fig. 2 shows an implantable stimulating device 22 which by wire or RF antenna stimulates cells in a remote vascularly implanted stent 18 to release a drug. Claim 1 as amended is distinguished in that it requires the control circuit to be implanted and proximate to the pump.

Further, Soykan is silent and disclosing nothing related to an implanted control circuit to control proper dosing and scheduling of said medicating agent in a closed loop control mode. Soykan is silent and disclosing nothing related to autonomously performance as determined by local homeostatic parameters. It cannot be held that Soykan discloses each and every element of claim 1 as amended.

Further, it should be noted that claim 1 has been amended to include multiple pumps, pouches and medicating agents which are each controlled by the control circuit. This allows inter alia for complex simultaneous or sequential multiple drug treatments

with tumor arresting drug cocktails.

Applicant respectfully requests advancement of the claims to allowance.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June 27, 2007 by

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Signature

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Respectfully submitted,

Daniel L. Dawes
Registration No. 27,123
Myers Dawes Andras
& Sherman LLP
19900 MacArthur Blvd., 11th Floor
Irvine, CA 92612
(949) 223-9600